PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61L 2/20, B29C 71/00, D04H 13/00 — A1

(11) International Publication Number: WO 96/00093

(43) International Publication Date: 4 January 1996 (04.01.96)

(21) International Application Number: PCT/US95/07716

(22) International Filing Date: 26 June 1995 (26.06.95)

(30) Priority Data:
08/266,293 27 June 1994 (27.06.94) US

(71) Applicant: KIMBERLY-CLARK CORPORATION [US/US]; 401 North Lake Street, Neenah, WI 54956 (US).

(72) Inventor: COHEN, Bernard; 381 Lakeshore Drive, Berkeley Lake, GA 30136 (US).

(74) Agents: ALEXANDER, David, J. et al.; Kimberly-Clark Corporation, 401 North Lake Street, Neenah, WI 54956 (US).

(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: IMPROVED NONWOVEN BARRIER AND METHOD OF MAKING THE SAME

(57) Abstract

An ethylene oxide sterilizable nonwoven material which is subjected to charging, and more particularly, electrostatic charging is provided. The nonwoven materials may include laminate nonwovens wherein one or more layers are subjected to charging. The nonwoven material(s) may also be treated with an antistatic material before or after subjecting the same to charging.

IMPROVED NONWOVEN BARRIER AND METHOD OF MAKING THE SAME

FIELD OF THE INVENTION

The present invention is directed to bacterial barrier fabrics. More particularly, the present invention is directed to nonwoven bacterial barrier fabrics for use as, for example, sterilization wrap, surgical draping, surgical gowns, cover garments, such as over-suits, and the like.

BACKGROUND OF THE INVENTION

As is generally known, surgical gowns, surgical drapes, surgical face masks and sterile wrap (hereinafter collectively "surgical articles") have been designed to greatly reduce, if not prevent, the transmission through the surgical article of liquids and/or airborne contaminates. In surgical procedure environments, such liquid sources include the gown wearer's perspiration, patient liquids, such as blood and life support liquids such as plasma and saline. Examples of airborne contaminates include, but are not limited to, biological contaminates, such as bacteria, viruses and fungal spores. Such contaminates may also include particulate material such as, but not limited to, lint, mineral fines, dust, skin squames and respiratory droplets. A measure of a fabrics ability to prevent the passage of such airborne materials is sometimes expressed in terms of "filtration efficiency".

Many of these surgical articles were originally made of cotton or linen and were sterilized prior to their use in the operating room. Such surgical articles fashioned from these materials, however, permitted transmission or "strike-through" of various liquids encountered in surgical procedures. In these instances, a path was established for transmission of biological contaminates, either present in the liquid or subsequently contacting the liquid, through the surgical article. Additionally, in many instances

provided by the present invention and will become more apparent upon further review of the following specification and claims.

SUMMARY OF THE INVENTION

In response to the above problems encountered by those of skill in the art, the present invention provides an ethylene oxide sterilizable polymer web, such as, for example, a nonwoven fabric. The webs of the present invention are formed by subjecting a portion of the web to charging, and more particularly to electrostatic charging, and then ethylene oxide sterilizing the web. The web may be subjected to charging followed by ethylene oxide sterilization or ethylene oxide sterilization followed by charging. The web may also be treated with an antistatic material before or after subjecting the web to charging.

The above web may further include a second web in a juxtaposed relationship to the first web. The second web may be formed from polymer fibers wherein a portion of these fibers may be subjected to charging. An antistatic treatment may also be present about portions of the second web.

DETAILED DESCRIPTION OF THE INVENTION

Disclosed herein are compositions, and methods of making the same, which improved both the airborne contaminate barrier and filtration efficiency of a web. The web of the present invention may be formed from polymer fibers, films, foams or a combination thereof. The films and foams may be porous or non-porous.

Among the applications for such compositions and methods are included, but not limited to, applications requiring sterilizable, breathable materials having high airborne contaminate barrier properties. Such materials have application in surgical articles, such as gowns, drapes, sterile wrap and face mask, as well as other non-surgical

laminate. Generally, the two outer layers provide the nonwoven fabric with strength while the inner layer provides barrier properties.

Suitable webs may be formed from a single layer or multiple layers. In the case of multiple layers, the layers are generally positioned in a juxtaposed or surface-to-surface relationship and all or a portion of the layers may be bound to adjacent layers. In the case of a nonwoven web, the nonwoven web may be formed from a plurality of separate nonwoven webs wherein the separate nonwoven webs may be formed from single or multiple layers. In those instances where the web includes multiple layers, the entire thickness of the web may be subjected to charging or individual layers may be separately subjected to charging and then combined with other layers in a juxtaposed relationship to form the finished web.

There are many well known methods of subjecting a material to charging, and particularly electrostatic charging. These well known methods include, for example, thermal, liquid-contact, electron beam and corona discharge methods. The method used for electrostatically charging the materials discussed in the Examples 1 and 2 (below) is the technique disclosed in U.S. Patent Application No. 07/958,958 filed October 9, 1992 which is assigned to the University of Tennessee, and is herein incorporated by reference. This technique involves subjecting a material to a pair of electrical fields wherein the electrical fields have opposite polarities.

Sterilization of the web may also be accomplished by ethylene oxide sterilization. In those instances when it is desired to sterilize surgical instruments by ethylene oxide, the surgical instruments may be wrapped in a nonwoven web. The entire package may then be subjected to an ethylene oxide sterilization cycle. When the ethylene oxide sterilization cycle is completed, the instruments, still wrapped, are then removed from the ethylene oxide sterilizing equipment and are stored in the wrapping

B. STERILIZATION

Process Parameters	Set Point
Chamber Temperature during exposure	130.0 F
Chamber Temperature at all other times	130.0 F
Initial Evacuation	1.2" Absolute
Leak Test	1.2" Absolute
Leak Test Dwell	5 minutes
Nitrogen Dilution	3.2" Absolute
Evacuation	1.2" Absolute
Humidity Injection Pressure Increase to	2.9" Absolute
Humidification Dwell Time	30 minutes
ETC Injection Pressure	15" Absolute
Time to inject gas	NA
Cycle Exposure	2 hours
Exposure Pressure	15" Absolute
Exposure Temperature	130.0 F
1st Re-evacuation	6.0" Absolute
1st Nitrogen Inbleed	50.0" Absolute
2nd Re-evacuation	1.6" Absolute
2nd Nitrogen Inbleed	50.0" Absolute
3rd Re-evacuation	1.6" Absolute
3rd Nitrogen Inbleed	50.0 Absolute
4th Re-evacuation	1.6" Absolute
Air Inbleed	To Atmospheric Pressure

Example 1

Kimberly-Clark manufactures a series of single sheet laminate nonwoven web materials made from three layers of fibrous material, i.e., spunbond-meltblown-spunbond (SMS) layers. These materials are available in a variety of basis weights. The two nonwoven webs used in these Examples were such single sheet laminate materials sold by Kimberly-Clark. Each of the nonwoven webs had a basis weight of 2.2 osy (ounces per square yard). Both spunbond layers had a basis weight of 0.85 osy and the meltblown layer had a basis weight of 0.50 osy. One of the nonwoven webs was a ZELEC® treated laminate and is sold by Kimberly-Clark the under the mark KIMGUARD® Heavy Duty Sterile Wrap and is designated in Table I as "KIMGUARD®".

The other nonwoven web, designated in Table I as "RSR" also had a basis weight of 2.2 osy but was not treated with an antistatic material. Both spunbond layers had a basis weight of 0.85 osy and the meltblown layer had a basis weight of 0.50 osy.

The method used to subject these webs to electrostatic charging (electret treating) is described in the above referenced U.S. Patent Application No 07/958,958.

The surface charge for both KIMGUARD® and RSR fabrics were analyzed and the data reported in Table I. The charge data for each side of these fabrics was recorded for both before ("AS RECEIVED") and after charging ("ELECTRETED"). Charge data were also recorded for ethylene oxide sterilized fabric samples which were first charged and then ethylene oxide sterilized ("AFTER EO TREATMENT"). As noted in Example 1, the KIMGUARD® samples were treated with ZELEC® and the RSR samples were not. Charge measurements were taken at 36 separate surface locations on each sample. For the categories, i.e., "AS RECEIVED" and "ELECTRETED", the KIMGUARD® and RSR samples were each single large sheets of material. Each such sheets were then portioned into several smaller samples. Sterilization and filtration data

TABLE I

Material	Side	As Received	Electreted	After EO Treatment Sample 1	Sample 2	Sample 3
KIMGUARD® (ZELEC®)	A	-2.8	-125	-4.2	27.2	-
	B	+1.6	- 15	24.1	-5.4	-
RSR (Non-ZELEC®)	A	- 61	+272	-89	-130	-138
	B	- 87	-432	-90	- 46	+ 54

through a sample compared to the number CFUs passing through the challenge control filter material. This value was derived by subtracting the number of CFUs passing through a sample from the number of CFUs passing through the challenge control filter material. The difference in the number of CFUs passing through these materials is then divided by the number of CFUs passing through the challenge filter material and then multiplied by 100 to convert to percent.

Table II

Sample	Nelson BFE	Microbial Challenge BFE
KIMGUARD®/Electret/EO	97.51+/-0.39	96.44+/-4.51
KIMGUARD®/EO	89.96+/-1.04	79.04+/-6.50

Table III summarizes the average Nelson BFE and the Microbial Challenge BFE categories for the RSR nonwoven materials. The procedures for both the Nelson BFE and Microbial Challenge BFE for the RSR materials were identical to the Nelson BFE and Microbial Challenge BFE procedures describe above. "RSR/Electret/EO" stands for RSR electret-treated then ethylene oxide-treated samples. "RSR/Electret" stands for RSR electret-treated samples. "RSR/EO" stands for RSR ethylene oxide-sterilized samples. 15 samples of each class of RSR material described above were analyzed and the results averaged.

TABLE III

Sample	Nelson BFE	Microbial Challenge BFE
RSR/Electret/EO	96.92+/-0.91	97.56+/-0.83
RSR/Electret	95.75+/-0.60	98.91+/-0.64
RSR/EO	79.73+/-3.20	79.82+/-5.96

Example 2 demonstrates that barrier properties of an ethylene oxide sterilizable material are improved when such material is first subjected to charging, and particularly

What is claimed is:

1. A method of manufacturing a web comprising:
charging the web; and
ethylene oxide sterilizing the web.

2. The method of claim 1 wherein the web is a nonwoven web and is ethylene oxide sterilized prior to being charged.

3. The method of claim 2 wherein the nonwoven web is charged prior to being ethylene oxide sterilized.

4. The method of claim 2 wherein the charging is electrostatic charging.

5. The method of claim 1 further including the step of treating the web with an antistatic material.

6. The method of claim 1 wherein the web comprises first and second nonwoven webs joined together in juxtaposed relationship.

7. The method of claim 6 wherein the webs are joined after the charging step.

8. The method of claim 7 wherein the first web is charged and the second web is not charged.

9. The method of claim 6 wherein the first web is treated with an antistatic material.

10. The method of claim 9 wherein the second web is treated with an antistatic material.

11. An ethylene oxide sterilized web wherein portions of the web have been subjected to charging.

INTERNATIONAL SEARCH REPORT

International Application No
PC./US 95/07716

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L2/20 B29C71/00 D04H13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L B29C D04H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 391 725 (JOHNSON & JOHNSON) 10 October 1990 see claims 1-5 ---	1,4-7, 10,17
Y	US,A,4 761 326 (BARNES C.G.) 2 August 1988 see column 1, line 8 - line 15; claims 1-22 ---	1,4
Y	DATABASE WPI Week 8324 Derwent Publications Ltd., London, GB; AN 83-57499K & JP,A,58 076 118 (KOKEN KK) , 9 May 1983 see abstract --- -/--	1,5-7,9, 10

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 1995	15. 11. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Peltre, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

formation on patent family members

International Application No
PC./US 95/07716

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-391725	10-10-90	AT-T-	107494	15-07-94
		AU-B-	5295390	11-10-90
		CA-A-	2014053	07-10-90
		DE-D-	69010051	28-07-94
		ES-T-	2060027	16-11-94
		GR-A-	90100242	27-09-91
		JP-A-	3063046	19-03-91
US-A-4761326	02-08-88	EP-A-	0296701	28-12-88
US-A-4863785	05-09-89	CA-A-	1311997	29-12-92
		EP-A-	0370835	30-05-90
EP-A-550029	07-07-93	AU-B-	662028	17-08-95
		AU-A-	3006292	08-07-93
		CA-A-	2070588	01-07-93
		JP-A-	5279946	26-10-93
		ZA-A-	9209043	19-05-93
WO-A-8103265	26-11-81	AU-B-	536384	03-05-84
		AU-B-	7077681	07-12-81
		CA-A-	1188452	11-06-85
		EP-A,B	0051615	19-05-82